# DMHAS OOC IRB REVIEWER CHECK LIST – Participation of Children

**Title of Study: _____ Date of Review: _____**

**Reviewer: _____**

| Checklist | Comment |
|---|---|
| **The study represents one of the following permissible categories of research:**<br><br>☐ Research not involving greater than minimal risk<br><br>☐ Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants<br><br>☐ Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition<br><br>☐ Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children | ***Minimal risk is defined as:*** probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. |

| Checklist<br><br>**46.404 Research Involving Not Greater than Minimal Risk**<br>*All questions must be answered yes in order to approve* | y | n | Comment |
|---|---|---|---|
| The research involves not greater than minimal risk | | | |
| Adequate provisions have been made to solicit assent of the children as set forth in 46.408 (see note at bottom of checklist) | | | |
| Adequate provisions have been made to solicit permission of the parent or guardian as set forth in 46.408 (see note at bottom of checklist) | | | |

| Checklist<br><br>**46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants**<br>*All questions must be answered yes in order to approve* | y | n | Comment |
|---|---|---|---|
| The risk is justified by the anticipated benefit to the participants | | | |
| The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches | | | |
| Adequate provisions have been made for soliciting the assent of the children as set forth in 46.408 (see note at bottom of checklist) | | | |
| Adequate provisions have been made to solicit permission of the parent or guardian as set forth in 46.408 (see note at bottom of checklist) | | | |

| Checklist<br><br>**46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition**<br>*All questions must be answered yes in order to approve* | y | n | Comment |
|---|---|---|---|
| The risk represents a minor increase over minimal risk | | | |
| The intervention or procedure presents experiences that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations | | | |
| The intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition which is of vital importance for the understanding or amelioration of the participant's disorder or condition | | | |

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|---|---|---|---|
| Adequate provisions have been made to solicit assent of the children as set forth in 46.408 (see note at bottom of checklist) | | | |
| Adequate provisions have been made to solicit permission of the parent or guardian as set forth in 46.408 (see note at bottom of checklist) | | | |

| **Checklist**<br><br>**46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children**<br>*Requires consultation by Secretary* | **y** | **n** | **Comment** |
|---|---|---|---|
| (a)The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or (2) the following:(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;(ii) the research will be conducted in accordance with sound ethical principles;(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408. | | | |

**46.408 Requirements for permission by parents or guardians and for assent by children** (a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary

condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §46.406 and §46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.